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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,158	09/15/2003	Frederic DeSauvage	11669.123USC1	4053

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,158	DESAUVAGE ET AL.	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. Claims 3-5 link Groups II-VII. Claims 15 and 16 link Groups VIII-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 3-5; and claims 15 and 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claims 1 and 2, drawn to a method of enhancing, stimulating, or potentiating differentiation of T-cells using a TCCR antagonist, classified in class 530, subclasses 300, 350, and 388.22.

II. Claim 6, drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is a small molecule, classified in class 424, subclass 85.1.

III. Claims 7 and 8, drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is an antisense RNA oligonucleotide, classified in class 514, subclass 44.

IV. Claims 7 and 9, drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is an antisense DNA oligonucleotide, classified in class 514, subclass 44.

V. Claim 10 drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is a TCCR variant lacking biological activity, classified in class 424, subclass 85.1.

VI. Claims 11-13, drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is a monoclonal antibody, classified in class 424, subclass 141.1.

VII. Claim 14, drawn to a method of treating a Th-1 mediated disease using a TCCR antagonist, wherein the antagonist is a TCCR ligand, classified in class 424, subclass 85.1.

VIII. Claim 21, method of preventing, inhibiting, or attenuating the differentiation of T-cells using a TCCR agonist, wherein the agonist is a small molecule, classified in class 424, subclass 85.1.

IX. Claim 22, drawn to a method preventing, inhibiting, or attenuating the differentiation of T-cells using a TCCR agonist, wherein the agonist is a TCCR variant with biological activity, classified in class 424, subclass 85.1

X. Claims 23-25, drawn to a method of preventing, inhibiting, or attenuating the differentiation of T-cells using a TCCR agonist, wherein the agonist is a monoclonal antibody, classified in class 424, subclass 141.1.

XI. Claim 26, drawn to a method of preventing, inhibiting, or attenuating the differentiation of T-cells using a TCCR agonist, wherein the agonist is a TCCR ECD, classified in class 424, subclass 85.1.

XII. Claims 17-19, drawn to a method of treating a Th-2 mediated disease using a TCCR polypeptide or agonist, wherein the disease is an infectious disease, classified in class 424, subclass 85.1.

XIII. Claims 17, 18 and 20, drawn to a method of treating a Th-2 mediated disease using a TCCR polypeptide or agonist, wherein the disease is an allergic disorder, classified in class 424, subclass 85.1.

XIV. Claim 27, drawn to a method for determining the presence of a TCCR polypeptide in a cell, classified in class 435, subclass 7.1.

XV. Claim 28, drawn to a method of diagnosing a Th-1 mediated or Th-2 mediated disease, classified in class 435, subclass 6.

XVI. Claims 29-31, drawn to a method for identifying a compound inhibiting expression of a TCCR polypeptide, classified in class 435, subclass 7.8.

XVII. Claims 32-34, drawn to a method for identifying a compound inhibiting biological activity of a TCCR polypeptide, classified in class 435, subclass 7.8.

3. Groups I-XVII are different methods.

4. Group I and Groups VIII-XI are different methods. Group I recites a method for enhancing differentiation of T cells using an antagonist. Groups VIII-XI recite a method for preventing differentiation of T cells using an agonist. The methods differ with

respect to endpoints, enhancing versus preventing differentiation of T cells; therefore, each method is patentably distinct.

5. Groups VIII-XI are different methods. The T cell agonists are different; small molecules, antibodies, and TCCR ECD differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

6. Groups I and VIII-XI and Groups II-VII, XII and XIII are different methods. Groups I and VIII-XI are methods for affecting T cell differentiation and Groups II-VII, XII and XIII are methods of treatment of disease. A method of affecting cellular differentiation and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

7. Groups II-VII and Groups XII and XIII are different methods. Groups II-VII are methods of treating Th-1 mediated diseases with a TCCR antagonist and Groups XII and XIII are methods of treating Th-2 mediated diseases with a TCCR agonist. The methods of treating the diseases differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

8. Groups II-VII are different methods of treating Th-1 mediated diseases. The T cell antagonists are different; small molecules, nucleic acids, antibodies, and TCCR ligand differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

9. Groups XII and XIII are methods of treating different Th-2 mediated diseases with a TCCR agonist. The diseases differ with respect to pathological conditions, etiologies

and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

10. Groups I-XIII and Groups XIV-XVII are different methods. Groups I-XIII are methods of treating disease or affecting differentiation of T cells. Groups XIV-XVII are drawn to methods of detecting a TCCR polypeptide, diagnosing disease, and identifying compounds affecting TCCR. These methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

11. Groups XIV-XVII are different methods. Group XIV, a method for determining the presence of a TCCR polypeptide is different from Group XV, a method of diagnosing a disease and different from Groups XVI and XVII, methods for identifying compounds inhibiting TCRR. Group XVI, a method for identifying compounds inhibiting expression of a TCRR peptide is distinct from Group XVII, a method for identifying compounds inhibiting biological activity of a TCRR peptide. These methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

12. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

13. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be

restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

14. This application contains claims directed to the following patentably distinct species of the claimed Groups II-VII. If Applicant elects one of these Groups, Applicant is further required to elect a species of Th-1 mediated disease, wherein the Th-1 mediated disease is:

A) autoimmune inflammatory, OR
B) allograft rejection

15. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

16. If the Applicant elects one of Groups II-VII, and **A**, wherein the Th-1 mediated disease is an autoimmune inflammatory disease, then Applicant is further required to elect species of autoimmune inflammatory disease, wherein the autoimmune inflammatory disease is:

A) allergic encephalomyelitis,
B) multiple sclerosis,
C) insulin-dependent diabetes mellitus,
D) autoimmune uveoretinitis,
E) inflammatory bowel disease, OR
F) autoimmune thyroid disease

17. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

18. This application contains claims directed to the following patentably distinct species of the claimed Group XII. If Applicant elects Group XII, Applicant is further required to elect a species of infectious Th-2 mediated disease, wherein the infectious Th-2 mediated disease is:

A) *Leishmania major*,
B) *Mycobacterium leprae*,
C) *Candida albicans*,
D) *Toxoplasma gondi*,
E) respiratory syncytial virus, OR
F) human immunodeficiency virus.

19. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

20. This application contains claims directed to the following patentably distinct species of the claimed Group XIII. If Applicant elects Group XIII, Applicant is further required to elect a species of allergic disorder as aTh-2 mediated disease, wherein the allergic disorder as a Th-2 mediated disease is:

A) asthma,
B) allergic rhinitis,
C) atopic dermatitis, OR
D) vernal conjunctivitis.

21. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

22. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

23. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

24. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

25. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

26. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

27. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.
Patent Examiner
8/9/2005

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
8/18/05